Kansas Department of Health and Environment

Smallpox Vaccination Program

Phase One

Section 1 - Organization and Management	
Management Personnel	
management rersonner	J
Timeline for Program Implementation	6
Section 2 - Identification of Public Health Smallpox Responses	
Section 3 - Healthcare Team Composition/Selection	
Timeline for Healthcare Smallpox Response Team Activities	10
Pre-Program Education	10
Post Vaccination Site Inspection / Adverse Events	11
Timeline for Vaccination of Healthcare Response Teams	11
Section 4 - Selection of Clinic Sites and Vaccination Team Section 5 - Pre-Event Vaccination Scheduling	
Total Persons to be Vaccinated Each Week	14
Strategy for Scheduling Vaccinations of Hospital Personnel	14
Section 6 - Vaccine Logistics and Security	14
Section 7 - Clinic Operations and Management	15
Ensuring Adequate Screening	15
Supplies, Equipment, and Educational Materials	15
Timeline for Implementing Clinic Operations	15
Section 8 - Vaccine Safety Monitoring, Reporting, Treatmand Patient Referral Section 9 - Smallpox Vaccine Program Training and	•
Education Plan	19
Vaccination Clinic Teams	19

Local Hospital Personnel	21
Section 10 - Data ManagementSection 11 - Communications	
Communications Goals and Objectives	24
Key Messages	25
Protocols for meeting routine, possible daily, information demands from m	edia
(e.g. # of vaccines administered, adverse events, etc.)	26
Identification of spokespersons for media and select audience communica	
	21
Detailed information on communication materials dissemination	27
Strategies for responding to communication crises	27
Establishment of general NSVP information hot line(s)	28
Coordination of communications	28
Tailoring messages and materials	28
Emerging communication issues	29
Protocol(s) to issue communications with the media	29
List of educational materials	29

Background and Assumptions

The Kansas Department of Health and Environment (KDHE) is ready to implement a "phase one" smallpox immunization activity targeting the following groups:

- a) public health workers in the state and some select local health agencies who may be activated to investigate the first case of smallpox in the state;
- hospital-based healthcare workers who may be involved in the management of a first case of smallpox.

Kansas has over 120 community hospitals, many of which are small institutions with fewer than 25 beds in rural communities. To keep the operations of phase one activities manageable and consistent with the guidelines issued by the CDC, immunization will be offered to hospitals in counties where there is a town with a population of 10,000 or more. Forty-three hospitals in 25 counties meet this criterion.

KDHE will retain the overall responsibility for the organization and implementation of the vaccination activities. Local Health Departments (LHD's) in the affected counties will be involved and asked to provide staff and other resources to support these activities.

The following assumptions were used in the development of this plan:

- a) An announcement from the federal government on the national plan and its goals will be made before 12-23-2002. This announcement will include clear directions and guidance for the implementation of the program.
- b) The smallpox vaccine will be available for KDHE by the end of January 2003.

If these assumptions change, the implementation schedule described in this plan may need to be adjusted. In addition, this plan is based on a *preliminary* assessment of how many hospitals in the state meet the criteria to be included in the program, and on preliminary figures from those hospitals of how many eligible employees they have. Hospitals have not yet communicated whether they accept to participate and how many employees are willing to consider being immunized. *Therefore the numbers in this plan are subject to change.*

Section 1 - Organization and Management

The Bureau of Epidemiology and Disease Prevention's (BEDP) Bioterrorism Program and Immunization Program within KDHE will be responsible for the operation and management of the smallpox immunization program. Other sections within the BEDP will assist with planning, implementation, and staffing, in particular the Epidemiologic Services Section. The KDHE Office of Local and Rural Health (OLRH), where the Hospital Bioterrorism Preparedness Program is located, will also be instrumental in the planning, implementation and staffing of phase one of the pre-event vaccination activities. The Bioterrorism Advisory Committee provided some input regarding the scope and focus of phase one activities prior to the design of the plan by the *Smallpox*

Vaccination Program Workgroup. This group was formed in November 2002 and includes the following members:

Gianfranco Pezzino, MD, MPH, Medical Director, BEDP Mindee Reece, Director, Bioterrorism Program, BEDP

Richard Morrissey, Director, OLRH

Gail Hansen, DVM, Director, Epidemiology Program, BEDP

Shirley Orr, RN, Director, Local Health Program, OLRH

Sue Bowden, RN, Director, Immunization Program, BEDP

Tom Clements, MD, Medical Bioterrorism Epidemiologist, Epidemiologic Services Section, BEDP

Mary Rapp, HAN Project Manager, Bioterrorism Program, BEDP

Sandy Johnson, NPS Manager, Bioterrorism Program, BEDP

Don Brown, Risk Communication Specialist, Bioterrorism Program, BEDP

Mike Heideman, Writer/Editor, Bioterrorism Program, BEDP

Denice Curtis, DDS, MPH, Sr. Epi Trainer, Bioterrorism Program, BEDP

Linda Frazier, RN, Distance Learning Coordinator, OLRH, BEDP

Terri Ploger McCool, Bioterrorism Training Coordinator, OLRH

Susan Morris, Hospital Bioterrorism Preparedness Program Coordinator, OLRH

Management Personnel

Coordination of the smallpox vaccination program will be the responsibility of the director of the immunization Program until a Public Health Nurse III position can be created and hired with bioterrorism funding to assume those responsibilities. The new position will be within the immunization Program to assure ongoing communication between the immunization and Bioterrorism Programs, since the healthcare community views the Immunization Program as a source of information for smallpox immunization issues. The immunization nursing staff comprises the core group of vaccinators for phase one of the pre-event program. Management personnel information is found in Table 1.

Table 1 – Management personnel for the Kansas smallpox vaccination program

Position Title	Program Function	Name	Contact Information
Medical Director	Provides direction	Gianfranco	1000 SW Jackson, Ste 210
	and oversight of	Pezzino, MD,	Topeka, KS 66612
	program activities	MPH	785 296-6179
			785 291-3775 fax
			gpezzino@kdhe.state.ks.us
Clinic	Coordinates clinical	Sue Bowden,	1000 SW Jackson, Ste 210
Coordinator and	activities and	RN	Topeka, KS 66612
smallpox	assures appropriate		785 296-0687
immunization	training and		785 296-5591 fax
program	competence of clinic		sbowden@kdhe.state.ks.us
manager	staff.		
NPS Manager	Coordinates vaccine	Sandy Johnson	1000 SW Jackson, Ste 210
	storage and handling		Topeka, KS 66612

		20 1-2-2003	1
	and assures availability of supplies necessary for clinic operation.		785 291-3065 785 291-3775 fax sjohnso1@kdhe.state.ks.us
Training Coordinator	Designs strategies and coordinates activity to assure that educational needs of vaccination providers and consumers are met.	Terri Ploger- McCool	1000 SW Jackson, Ste Topeka, KS 66612 785-291-3796 785-296-1231 tplogerm@kdhe.state.ks.us
Distance Learning Coordinator	Facilitates and communicates training opportunities through satellite teleconferencing and webcast media.	Linda Frazier, RN	2301 E 13 th St Hays, KS 785 625-5663 785 625-4005 fax Ifrazier@kdhe.state.ks.us
Medical Epidemiologist	Identifies and educates KDHE rapid response teams. Provides medical consultation and assures vaccination safety monitoring.	Tom Clements, MD, MPH	1000 SW Jackson, Ste 210 Topeka, KS 66612 785 296-6215 785 291-3775 fax tclements@kdhe.state.ks.us
Risk Communication Specialist	Provides the public with necessary information regarding vaccination activities.	Don Brown	1000 SW Jackson, Ste 210 Topeka, KS 66612 785 368-8053 785 291-3775 fax dbrown@kdhe.state.ks.us
Hospital Liaison	Primary contact for hospital communications and scheduling.	Susan Morris	1000 SW Jackson, Ste 340 Topeka, KS 66612 785-296-5201 785-296-1231 samorris@kdhe.state.ks.us
Data Management Coordinator	Coordinates development of information system and assures that vaccination data is captured and submitted as required.	Mary Rapp	1000 SW Jackson, Ste 210 Topeka, KS 66612 785 296-6522 785 291-3775 fax mrapp@kdhe.state.ks.us

Timeline for Program Implementation

The smallpox vaccination program workgroup will meet regularly to monitor the progress of the activities and assess timelines.

Table 2 – Timeline for smallpox program implementation in Kansas

Timeframe	Activities
12/2/2002	Select target hospitals and counties.
12/5/2002 –	All team members will observe the CDC Bioterrorism Update:
12/6/2002	Smallpox Preparedness either live or taped.
12/9/2002 -	Assign responsibilities for program functions.
12/3/2002 —	Submit pre-event plan to CDC.
12/13/2002	Identify potential vaccination sites.
	Identify materials /supplies needed for clinic operations and
	investigate sources for procurement.
	Submit orders for materials/supplies.
	Recruit/confirm vaccination clinic staff.
	Create template/checklist of all local responsibilities for
	administering the smallpox vaccination program.
12/16-2002 –	Continue supply acquisition.
12/20/2002	Define the core functions of Clinic Vaccination Administration
12/20/2002	and identify competencies.
	Compile current educational material on pre- and post- smallpox
	vaccination activities.
	Send three BEDP staff members to CDC train-the-trainer
	session.
	Continue to compile current educational material on pre- and
	post- smallpox vaccination activities.
	poor smallpox vaccination activities.
12/23/2002 –	Continue supply acquisition.
12/27/2002	
	Complete supply acquisition.
12/30/2002 –	Organize clinic supplies in units of 100 each in preparation for
01/10/2003	transport to clinic sites.
	Assure security, safety and quality for vaccine storage through
	installation of alarm and lock for refrigeration equipment at
	central storage facility.
	Develop training objectives and content for each core function.
	Prepare invitation letters to hospital "leads" to market the training
TBD	in Parsons, Kansas City, KS, Topeka, Garden City, Great Bend
(after CDC	and Wichita.
finalizes	Identify dates, secure logistics for the six training sessions.
Training	Identify the KDHE training cadre and finalize itinerary.
materials and	Prepare training packets.
notifies KDHE)	Provide KDHE vaccinator staff and rapid response staff with
,	informed consent forms.
	Begin distribution of education/informed consent materials to
	targeted hospitals and LHDs.
	Medical Screeners will be trained to assess medical conditions
	for potential vaccines, normal and adverse reactions to vaccine,

	Upualeu 1-2-2005		
	KDHE vaccinators will be trained (in-house) on smallpox		
	vaccination techniques.		
	Train Clinic staff (non-vaccinators).		
	Conduct a mock vaccination clinic to assess competencies.		
02/03/2003-	Obtain commitment to participation from hospitals.		
02/07/2003			
Two Week s following the release of materials	Begin hospital/LHD training in Parsons, Kansas City, KS, Topeka Informed consent and risk/benefit education is provided to potential vaccinees. Select vaccination clinic locations.		
Three weeks following the release of materials	KDHE Vaccinators and response teams will be vaccinated.* Conclude training in Garden City, Great Bend, and Wichita. Continue informed consent and risk benefit education to potential vaccinees. Select vaccination clinic locations.		
Week 0 (Zero)	Hospitals /LHDs prepare lists of individuals to be vaccinated during week one and forward to KDHE by the end of the week.		
Week 1 **	Vaccination begins in Topeka, Parsons and Kansas City, KS.		
Week 2	Vaccination begins in Wichita and Overland Park.		
Week 3	Vaccination begins in Garden City, Great Bend, and McPherson.		
Week 4	Vaccination continues in Topeka, Parsons and Kansas City, KS.		
Week 5	Vaccination continues in Wichita and Overland Park.		
Week 6	Vaccination continues at Garden City, Great Bend, and McPherson.		
Week 9	Catch Up Clinic: Vaccination site in Topeka remains open to vaccinate any remaining phase one personnel and revaccinate individuals with vaccine failures.		

Currently anticipated for 1-27-2003 Currently anticipated for 2-10-2003

Section 2 - Identification of Public Health Smallpox Response Teams

The Kansas Smallpox Rapid Response Team will consist at this initial stage of only KDHE personnel. Supervision, management, and support of the team will be the responsibility of the State Epidemiologist. Personnel staffing will be composed of a physician team leader, an epidemiologist, a laboratory scientist or technician experienced in handling viral specimens, and the designated medical investigator and nurse (all of whom are either RNs or highly experienced public health LPNs) in whose region the response is required.

The following are identified as members and alternates:

Position	Primary Team	Alternates
Team Leader	Gianfranco Pezzino, MD,	Thomas Clements, MD, MPH
	MPH	
Epidemiologist	Denice Curtis, DDS, MPH	Renee Funk, DVM, MPH
Nurse	As Determined	As Determined
Laboratory	As Required	As Required
Scientist		
Medical	As Determined	As Determined
Investigator		

All members of the team will be vaccinated.

Only one team will be formed at this time. Team members, their alternates, and the clinic "vaccinators" will be vaccinated during the same clinic.

In accordance with the planning guidance provided by the CDC, the Laboratory Response Network (LRN) consists of 50 laboratories across the state functioning at the "Level A" or "Level B" level. The Diagnostic Microbiology section of the KDHE Division of Health or Environmental Laboratories is trained to fulfill the role of the highest level of diagnostic capability. With the installment of new hoods and advanced training of eight technicians, the KDHE laboratory is considered a "Level B" diagnostic laboratory.

Section 3 - Healthcare Team Composition/Selection

There will be 43 healthcare response teams in Kansas initially vaccinated for smallpox. The teams will be located within the 43 community hospitals in counties in which a city of 10,000 or more persons exists, with the addition of a limited number of public health workers from local health departments supplementing the team as needed. Public health workers will consist of disease investigators and nursing staff. The hospital teams will be composed of the following types of workers (as recommended by the national Advisory Committee on Immunization Practices):

- ✓ Emergency Room Staff, including physicians and nurses
- ✓ Intensive Care Staff, including physicians and nurses
- ✓ General Medical Unit Staff, including physicians and nurses
- ✓ Medical House Staff
- ✓ Medical Sub-specialists
- ✓ Infection Control Staff
- ✓ Respiratory Therapists
- ✓ Radiology Technicians
- ✓ Security Personnel
- ✓ Housekeeping Staff

Each hospital will be allowed to choose its own team composition, following the outline provided to hospital administration in a KDHE letter outlining the process sent to facilities through the Kansas Hospital Association on 11/27/2002. It is expected that the vast majority of the potential vaccinees will be physicians and nurses.

While the main purpose of each rapid response team is to care for smallpox patients in the team's institution, work is in progress to expand the concept of a rapid response team from a single institution to a regional approach. It is hoped that as a result of these regionalization planning efforts the response teams will be able to assist in situations outside of their institutions, when necessary.

Timeline for Healthcare Smallpox Response Team Activities

On 12/02/2002 KDHE, in conjunction with the Kansas Hospital Association held a conference call with the selected hospitals and discussed the process including preprogram education activities and the need for follow-up vaccination site inspection and adverse event reporting and treatment. At that time KDHE collected an estimate of the number of potential workers needing vaccination as a part of the phase one process. That listing is included as Appendix 1. The selected hospitals were asked at that time to provide the KDHE Hospital Bioterrorism Program Manager with information regarding their intent to participate or not in the program by 12/13/02. Additionally, hospitals are to submit their detailed lists of persons needing vaccination to the smallpox education coordinator at least two weeks in advance of the clinic scheduled in their area.

Pre-Program Education

Pre-program education will be provided to hospital and local public health department representatives by KDHE. The training will include a combination of written, video, and online material, as well as face to face training at six training sessions throughout the state at least two weeks prior to the actual clinic, and at the eight vaccination sites immediately before the beginning of the clinic's activities. The details of the training activities are discussed in section 9. Pre-program education will also be provided to the local health department representatives as a part of the same training. The education will consist of sufficient information to allow individuals to evaluate the risks and benefits of vaccination and assess contraindications for vaccination. Public health staff will be

available to answer questions that potential vaccinees may have regarding risk or the vaccination process itself. Each hospital facility participating in phase one activities will be asked to submit to KDHE the name(s) of the individual responsible for pre-event screening and informed consent education at that facility.

KDHE has provided the hospital and local public health entities with a secure forum for asking questions regarding the process through the Public Health Information Exchange (PHIX) program. Each of the selected hospitals and public health departments has access to the PHIX secure website and may post questions and receive answers to questions regarding the process. In addition, PHIX is the vehicle that KDHE uses to disseminate information regarding smallpox planning to the hospital and public health departments. For a description of PHIX please see Appendix 2.

Post Vaccination Site Inspection / Adverse Events

Both post vaccination site inspection and treatment and reporting of adverse events will be the responsibility of the hospital or local public health department employing the vaccinees. Each hospital facility and local health department participating in phase one activities will be asked to submit to KDHE information on who will be responsible for assuring that adequate vaccine site inspection is accomplished and the name of a physician who will be the point of contact in the event of severe adverse reactions at that facility. KDHE will, through PHIX and "follow-up kits" provided to employers, provide appropriate assistance and guidance so that follow-up to vaccination is accomplished and documented. KDHE has planned two vaccination clinic cycles for each hospital to minimize the number of employees potentially unable to work at the same time. Through this process KDHE will also be able to assess the monitoring system of each site upon the return of the vaccination team for the second clinic.

Timeline for Vaccination of Healthcare Response Teams

The timeline for selection of hospitals and vaccination of healthcare response teams is as follows:

Timeframe	Activities
Dec 2, 2002	Eligible hospitals are identified.
Dec 13, 2002	Hospitals must inform KDHE of their decision regarding
	participation in the pre-event vaccination program.
Two weeks in	Informed consent and risk/benefit education is provided to the
advance of	potential vaccinees.
scheduled clinic	Hospitals /LHDs prepare lists of individuals and forward to
	KDHE.
Presidential	KDHE requests vaccine from NPS.
announcement	KDHE response team(s) receive vaccine.
Week 1 *	Vaccination begins at sites in Topeka (425 persons), Parsons
	(175 persons), and Kansas City KS (250 persons).
Week 2	Vaccination begins at sites in Wichita (375 persons), and
	Overland Park (350 persons).

Week 3	Vaccination begins at sites in Garden City (200 persons),
	Great Bend (200 persons), and McPherson (225 persons).
Week 4	Vaccination continues at sites in Topeka (425 persons),
	Parsons (175 persons), and Kansas City KS (250 persons).
Week 5	Vaccination continues at sites in Wichita (375 persons) and
	Overland Park (350 persons).
Week 6	Vaccination continues at sites in Garden City (200 persons),
	Great Bend (200 persons), and McPherson (225 persons).
Week 9	"Catch up" vaccination site in Topeka remains open to
	vaccinate any remaining phase one personnel and
	revaccinate individuals with vaccine failures.

^{*} Currently anticipated for 2-10-2003

Section 4 - Selection of Clinic Sites and Vaccination Teams

KDHE will operate eight vaccination clinic sites. The sites will be located in Topeka, Kansas City, Wichita, Great Bend, Parsons, Overland Park, McPherson, and Garden City. These sites were selected with the goal of providing a clinic within a two-hour drive from each hospital participating in the pre-event vaccination program.

All vaccine, supplies, and equipment will be stored at the Vaccine Depot in the KDHE offices in Topeka. Clinic teams will deploy to clinic sites with the amount of vaccine and supplies necessary for vaccinating the number of personnel expected at the clinic on that day. Only one clinic will be operational at any given time.

The local health departments in the counties where vaccinations will occur will be asked to identify potential vaccination sites and provide that information to KDHE. KDHE staff will evaluate the potential sites and select the sites that will be used by December 27, 2002.

The staffing positions for the Vaccination Teams are tentatively identified in Table 3. Key team members will be KDHE employees who have already been identified. The KDHE staff will work side by side with local health department staff in the various roles. This will be an opportunity to train local health departments on the operations and management of a smallpox vaccination clinic. In case local health departments are not able to provide the suggested staff as described in Table 3, KDHE will make efforts to increase state-based personnel for that clinic. A diagram of a clinic's work flow is in Appendix 3.

All KDHE personnel will be trained on their clinic roles prior to implementation as noted in Table 2. Local health department staff will receive "On the Job" training immediately before and during the clinic operations. All local health departments that participate in the Pre-event vaccination clinics will receive educational and orientation materials prior to the activation of the clinic sites. Additional details regarding the clinic operations training can be found in Section 9.

Table 3 - Pre-Event Smallpox Vaccination Staffing

Position	Туре	Total Number Needed	Number provided by KDHE	Number Needed from Local Health Departments
Vaccinator	Vaccinated (Pre- event) Public Health Personnel	4	4	0
Vaccination Helper	Public Health Staff	4	0	4
Greeters	Administrative	2	1	1
Registration	Administrative	2	1	1
Medical Screening	Public Health Nurse	6	3	3
Forms Collection and Exit Review	Administrative	2	1	1
Clinic Flow	Administrative	4	0	4
Medical Doctor	MD	1 (on-call)	1	0
Data Entry	Clerical	4	1	3
Total		29	12	17

The KDHE Immunization Program Director or her designee will supervise and manage the clinic operations. It is the responsibility of the clinic manager to assess the operations of the clinic and incorporate any necessary changes in future clinic operations. The clinic staff will complete an After Action Review report at the completion of each clinic. All staff will be asked to provide feedback to the clinic manager on process improvement. It is anticipated that the staffing and flow of the clinics may change after the first few clinics are completed.

Section 5 - Pre-Event Vaccination Scheduling

Total Persons to be Vaccinated Each Week

The estimates for total persons to be vaccinated each week are based on the current preliminary estimates from the eligible hospitals and assume an average of 5 individuals from each local health department in counties with selected hospitals. These estimates are subject to fluctuations up or down during the planning process. KDHE has planned two vaccination clinic cycles for each hospital to minimize the number of employees potentially unable to work at the same time. The current estimates are:

Cycle 1 - Week 1 -- 850 persons

Week 2 -- 725 persons

Week 3 -- 625 persons

Cycle 2 - Week 4 -- 850 persons

Week 5 -- 725 persons Week 6 -- 625 persons

TOTAL 4,400 persons

Strategy for Scheduling Vaccinations of Hospital Personnel

Once the pre-event vaccination process begins, clinics will be scheduled by KDHE staff. Each hospital and local health department involved in the process will be notified of the clinic(s) that their staff is to attend. The clinic assignment is based on two factors: geographic proximity to the vaccination site and number of persons to be vaccinated. The pre-assignment of a site allows for more effective planning and better utilization of human and vaccine resources. Sites were pre-located so that actual travel time is held to two hours or less. Actual appointments for vaccinations will be made the week before the clinic begins operations and will allow employers the flexibility of bringing larger numbers of their employees to the vaccination sites at the same time, thereby minimizing costs. Because the number of public health department workers will be minimal, those vaccinees will be given a copy of the clinic schedule and may schedule an appointment for the clinic of their choice.

Section 6 - Vaccine Logistics and Security

(Section 6 is not available to the general public. Law enforcement agencies and public health organizations are aware of the contents of this section. Releasing this information to the public could jeopardize the security of the vaccine and the safety of the clinic workers.)

Section 7 - Clinic Operations and Management

Ensuring Adequate Screening

The following was described in the Post-event Smallpox Plan recently submitted to the CDC:

- 1. KDHE will issue guidelines on target groups for pre-event immunization.
- 2. Hospitals will identify possible candidates.
- 3. Hospitals will educate and pre-screen identified candidates on the benefits and risks of the smallpox vaccination.
- 4. Candidates who accept to volunteer will be advised to consult with their personal physicians and receive tests to rule out contraindications.
- 5. Candidates who pass pre-screening will be placed on the eligible candidate list for the hospital.
- 6. Hospitals will send their eligible lists to KDHE.
- 7. KDHE will organize and manage lists from multiple hospitals.
- 8. KDHE will identify clinics to be used for vaccination and advise hospitals which clinics to use and of their allotted date and time for vaccination.
- KDHE's vaccination team will conduct the clinics and immunize health care workers.
- 10. Potential vaccinees will be re-screened by KDHE medical personnel prior to vaccination. This is to ensure recent medical events have not altered eligibility for vaccination. Consent forms will be signed and witnessed by a nurse.

Supplies, Equipment, and Educational Materials

KDHE staff are currently identifying and ordering the supplies and equipment that will be needed to operate the clinics. The intent is to have the team as self sufficient as possible, so that little support with supplies is needed locally.

Education and pre-screening materials will be provided to the hospitals that elect to participate in the program. Training packages provided by the CDC will be given to each hospital so that all personnel considering vaccination will be well educated on all aspects of the vaccination procedure. KDHE is currently in the process of setting up six regional training sessions that hospital teams could attend after reviewing the educational materials that were provided.

During vaccination activities educational materials will be available at the clinics. Vaccinees will have the opportunity to have any questions further clarified by KDHE staff at the clinic. A KDHE physician will be on-call to serve as a resource to potential vaccinees and KDHE nursing staff. Vaccine Information Sheets (VIS), site care information, and take recognition sheets will be given to all vaccinees.

Timeline for Implementing Clinic Operations

KDHE has developed a timeline for implementing clinic operations (see Table 1). KDHE staff will be trained prior to conducting clinic operations. Training for hospital

personnel will occur before they begin operating clinics. We are currently in the process of identifying potential clinic sites and would be ready to begin operating vaccination clinics soon after liability protection is extended and vaccine shipments arrive in Kansas.

Section 8 - Vaccine Safety Monitoring, Reporting, Treatment, and Patient Referral

Thomas I. Clements, MD, MPH, the KDHE Bioterrorism Program's Senior Medical Epidemiologist, has been identified as the Safety Manager responsible for coordinating vaccine safety monitoring, reporting, treatment, and patient referral for Kansas.

Vaccine safety monitoring begins before the actual vaccination. It begins with proper completion of the personal and demographic data at the vaccination clinic. To maximize accuracy, only trained personnel will be entering this data directly into a laptop computer on-site (see Sec. 10, below).

Clinic operations are described in Section 7. Hospitals will assign positions or employees responsible for post-vaccination monitoring and care, including the following:

- assess vaccine-site dressings for all vaccinated health care workers daily
- determine if dressings needs changing
- change the dressing if indicated
- assess the vaccination site for local reactions and for vaccine take
- provide a primary contact for reporting and evaluating adverse events related to smallpox vaccine, and
- reinforce messages to vaccinees about the need for meticulous handhygiene.

Mild side effects will be observed and treated by the hospital clinical staff. The HAWK Immunization Information System (see Section 10) will be enabled to collect information on mild side effects, and hospital staff will be encouraged to record this information in the system. For more severe side effects, the hospital staff will contact the KDHE Safety Manager (identified above) via the Epi Hotline and discuss the case with him. All the referrals KDHE will be recorded in the database. The Epi Hot-line is a 24-hour-aday, toll-free phone number (1-877-427-7317), and will be the point of contact for all hospitals to report or discuss post-vaccination adverse events. Should the KDHE Safety Manager need further consultation, he will contact a member of the Kansas Public Health Clinical Network and request consultation with the attending hospital physician.

The Kansas Public Health Clinical Network is being formed by the University of Kansas School of Medicine at the request of, and under the guidance of, KDHE. The network will consist of fully qualified clinicians in a number of specialties that would be knowledgeable of smallpox vaccination adverse events and their management. The network members will be scattered across the state and will have access to telemedicine capabilities. A description of the network is contained in Appendix 4. It is

envisioned that 15 to 20 clinicians will be on call 24/7 for requests from KDHE. A request for consultation from the attending physician to the Epi Hotline will be transferred to a physician epidemiologist to provide advice and assistance. The physician epidemiologist will triage any requests for consultation and contact a member of the network, when necessary. The network consultant will provide telephone consultation and determine if distance evaluation or bedside evaluation is required. A KDHE Regional Medical Investigator equipped with a high resolution, short focal length digital camera can be dispatched to the bedside to take photos and transmit them to KDHE or the consultant. More than 40 sites around the state have live video telemedicine capabilities to tie into the Medical Center that may be used, if needed.

It is anticipated that up to 46 patients may need consultation from the Kansas Public Health Clinical Network, as shown in Figure 1.

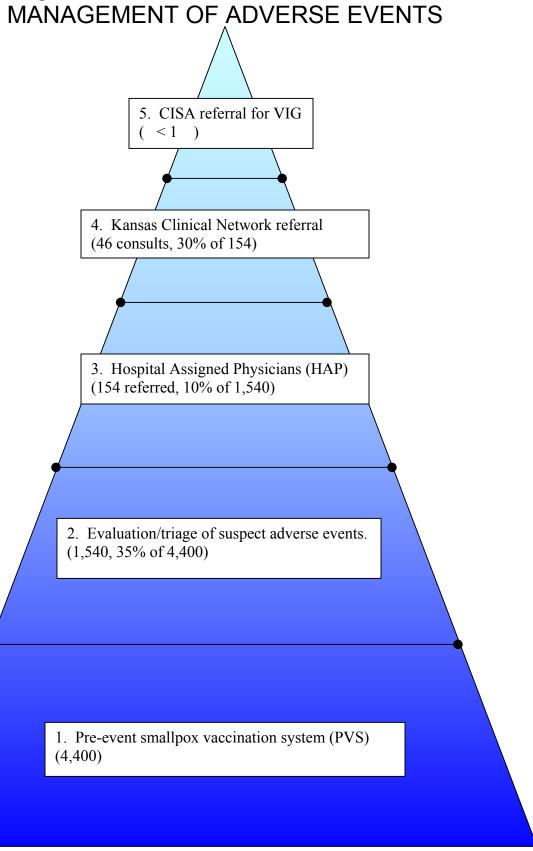
If the network consultant needs further consultation or surmises that VIG is needed, the Clinical Immunization Safety Assessment Team (CISA) at CDC will be consulted by KDHE. Should VIG or other evaluation be required by CISA the proper arrangements will be made. Adverse events that will be reported and tracked on the Kansas reporting system mentioned below and downloaded to CDC each night will include at the minimum the following:

Accidental implantation
Eczema vaccinatum
Generalized vaccinia
Erythema multiforme
Post-vaccinia encephalitis
Vaccinia keratitis
Bacterial infection

The events in the list above will also be reported to the VAERS. In addition, efforts will be made to collect information also on more mild vaccine side effects.

.





Section 9 - Smallpox Vaccine Program Training and Education Plan

The initial training process will focus on two audiences: vaccination clinic teams and local hospital personnel. Hospital training will include personnel serving as subject matter experts (for pre-event and post-event vaccination activities) and potential vaccinees.

Vaccination Clinic Teams

These team members will be comprised of state and local public health officials (see Section 4) and will be trained on critical components related to the overall smallpox vaccination plan in phase one, as well as clinic vaccination administration, clinical protocols, and procedures. The training team will consist of members of the smallpox planning workgroup.

Timeline for Training Implementation for Vaccination Teams

Timeframe	Activities	Point of Contact
12/05/02 -	**All team members observed the CDC	Linda Frazier,
12/06/02	Bioterrorism Update: Smallpox	Distance Learning
	Preparedness either live or taped	Coordinator
12/30/02 –	**Define the core functions of Clinic	Terri Ploger-McCool
01/10/03	Vaccination Administration and identify	BT Training
	competencies	Coordinator
	**Develop training objectives and	
	content for each core function	
12/16/02-	KDHE staff attend CDC training	
12/20/02		
01/13/03-	**The core team (KDHE)of vaccinators	Sue Bowden, Director
01/24/03	will be trained in-house on smallpox	Immunization
	vaccination techniques	Program
01/13/03-	**Implement vaccination team training	Denice Curtis
01/24/03	**Conduct a mock vaccination clinic to	Terri Ploger-McCool
	assess competencies	
01/13/03-	**Medical Screeners will be trained to	Dr. Tom Clements
01/24/03	assess medical conditions for potential	
	vaccines, normal and adverse reactions	
	to vaccine, and serve as a subject	
	matter expert in the regions.	

Training will include:

 Orientation and paperwork. How to greet and conduct initial orientation to vaccinees upon their arrival; provide information about the vaccination

process; distribute informational material and clinic documents; explain how to complete the documents and answer questions.

- Registration. Registration staff will become familiar with each of the forms to be distributed. They will check for forms completeness and accuracy.
- Referral. Referral personnel will be trained on how and when to refer persons to vaccination stations or to medical screeners.
- Form Collection. Staff will be trained to collect the forms from recipients before departure and verify the forms have been signed by the vaccination team, and entered the lot numbers on the appropriate documents.
- Medical Assessment. KDHE Bioterrorism Program physicians will train nurses on how to assess medical conditions that could prevent receipt of the vaccine, common reactions to the vaccine, and how to respond to medical emergencies.
- Clinic Supply Management. This role will be assigned to one specific person in each team. These staff will be trained on tracking availability of supplies and addressing safety issues regarding vaccine handling and storage.
- Data Entry. Staff will be trained on the minimum data elements that need to be entered into the system and how to submit data to PHIX on a daily basis after the vaccination process is over. They will also be trained on what steps to take in case forms are incomplete or illegible and to manage any other issues they may encounter while entering data.
- A mock vaccination clinic will be conducted in advance to identify any planning weaknesses and to assess the performance of clinic staff. Local health department personnel will be invited to participate in the mock clinic so that they may become familiar with clinic operations.
- The local health department (LHD) personnel will be trained by KDHE staff during regional training meetings to be conducted prior to clinic operations. Personnel will also be trained by their KDHE "partners" immediately prior to and during the actual clinic operations. Local health department personnel who elect to work in the clinics will also be provided "read ahead" materials so that they can be familiar with clinic management and operations.

Local Hospital Personnel

Hospitals will be asked to identify clinical staff (ie. a physician, nurse practitioner, infection control nurse, employee health nurse, or physician assistant) to be trained as subject matter experts for their hospital staff. These individuals will serve as a point of contact for state and local public health officials on any preand post-vaccination issues. They will need clinical information, including vaccine contraindications and pre-screening issues for potential vaccinees, vaccine follow-up care, evaluation of "takes," site care, and monitoring, and management and referral of adverse reactions following vaccination.

Timeline for Training Implementation for Hospital Personnel

Timeframe	Activities	Point of Contact
12/09/02 –	**Compile current educational material	
12/20/02	on pre- and post- smallpox vaccination activities	Denice Curtis
12/09/02 – 12/13/02	**Create template checklist of all local responsibilities for administering the smallpox vaccination program	Susan Morris
TBD (after CDC finalizes training materials	**Identify dates and secure logistics for a training tour at six clinic sites **Identify the KDHE training cadre and secure itinerary	Terri Ploger-McCool
TBD (after CDC finalizes training materials	**Prepare invitation letters to all hospital "leads" to market training tour	Susan Morris
TBD (after CDC finalizes training materials	**Prepare and send training packets	Terri Ploger-McCool
01/13/02- 01/24/02	**Assess need to schedule video conference(s)	Terri Ploger-McCool
Two weeks following release of training materials	**Conduct training tours at clinic sites	Susan Morris

Pre-event education to hospital staff will be provided through a variety of methods, most of them through long-distance education.

<u>Training packages</u> will be sent to each hospital team two weeks before vaccination starts. The training package will include:

"Smallpox: What Every Clinician Should Know"

"Smallpox Overview"

"Vaccine Overview"

"Reactions after Smallpox Vaccination"

"Adverse Reactions Following Smallpox Vaccination"

"Medical Management of Smallpox Vaccine Adverse Reactions"

Smallpox Vaccine Pre-screening

Video

Fact Sheet

Fact Sheet

"Medical Management of Smallpox Vaccine Adverse Reactions"

Fact Sheet

Information Packet

<u>Telephone or video conferences</u> will follow the distribution of the training packages. A panel of experts will be available to answer questions during five consecutive days for a period no longer than three hours each day. A schedule for the conferences will be sent together with the training packages.

<u>The Public Health Information Exchange (PHIX)</u> (Appendix 2) will serve as a forum for questions and will be monitored daily. The CDC frequently asked questions and answers regarding smallpox vaccination is posted on PHIX.

Section 10 - Data Management

Kansas has been on the cutting edge of using modern information technology tools for public health for several years. These tools have been successfully implemented in the state and will be used for smallpox planning and response activities, including pre-event immunization activities. It is our intention to select option 3 (perform data exchange with the CDC from a state system), as explained in the CDC guidance document for this activity.

Kansas does not have a Web-based, functional immunization registry at this time. The most helpful tool that we will use to build and run our smallpox immunization information system is HAWK. This is a secure, Internet-based disease reporting system that currently allows local health department staff to enter information on reportable diseases directly on-line. The system has a patient information module, a basic case record, and *extended screens* that can collect disease-specific information for selected conditions. HAWK includes 128-bit encryption through SSL technology. A more detailed description of HAWK can be found in Appendix 5.

HAWK will be used to record immunization information for all stages of the immunization process. An extended screen for *smallpox immunization* is already being developed. This will collect detailed information on each vaccination "event." A table with facility information is being added to the system, and the

HAWK administrators will centrally enter facility-specific information. Additional capabilities are also being added to capture vaccinator and vaccine batch data. Once this information is defined, a drop list in the smallpox immunization system screen will offer the user a choice of all the facilities included in the system where smallpox vaccination can be administered, a list to select approved vaccinators, and a list to select the current vaccine batch being administered. Information on vaccine "take" and adverse reactions will also be collected and linked to each vaccination event. More serious adverse events will be reported also to the Vaccine Adverse Event Reporting System (VAERS).

Another useful tool for data management will be the Public Health Information Exchange (PHIX, see Appendix 2). PHIX does not collect individual information, but text-based reports that can be shared with selected authorized users of the system. PHIX already has a restricted forum area dedicated to the discussion of issues about smallpox immunization. PHIX will be used to exchange information on phase one-related events and activities with local health departments and hospitals. The site is remotely accessible to administrators, and all administrative operations can be performed from the administrator's laptop.

To avoid undesirable interference with the HAWK disease reporting module, and to increase security, HAWK and the smallpox immunization systems will actually run in parallel, but will be separated. The development of the vaccination system will start from a copy of the current HAWK screens, stored procedures, and database, from where elements will be added (e.g., smallpox vaccination specific information) or dropped (e.g., x-ray or laboratory data), as needed. This will allow retaining the existing well tested, robust security and business rules in HAWK and avoiding the need to re-design and rebuild a new system for smallpox vaccination. The common point of access will be the current HAWK URL, from where the user will have the option to access either the disease reporting system or the smallpox vaccination system. The use of HAWK for immunization tracking purposes will also allow KDHE staff to easily analyze the data collected, including "take" rates and incidence of adverse events.

One of the limitations of HAWK as an information management tool is that it requires a live Internet connection, preferably over a high-speed line (although a dial-up connection is also a workable option). This connection may not always be available at the vaccination site during phase one. Therefore KDHE is developing an *off-line data entry tool* to allow local data entry of records that can be uploaded to the central database at a later time. This off-line tool is based on a Microsoft Access application developed at KDHE that mirrors the data elements in the central smallpox vaccination database. This Access tool will be installed on all laptop computers utilized for phase one activities. Users will enter new vaccination records into the off-line tool only. No new records will be generated using the online HAWK system. At the end of the day, the user will upload the Access file to the KDHE server using an encrypted file transfer option already built into PHIX. Subsequent updates of the record, including information

on "take" or adverse events, or creation of new vaccination records for existing individuals (i.e., second vaccination after vaccine failure), will only be conducted using online access to the system. This will avoid the need for a more complex two-way synchronization process.

For back up purposes, all paper forms used to enter the information at each clinic will be retained and stored in a secure site at KDHE. In addition, during offline data entry, an IBM Microdrive will be inserted in each laptop, and the Access database will be backed up automatically at short intervals. At the end of the day, the Microdrive will be removed and stored separately from the laptop.

Once the information is collected in HAWK, regular uploads to CDC (through its Secure Data Network, SDN) will take place, using the XML specifications provided by CDC. HAWK is already uploading weekly information through the SDN for surveillance reports.

In summary, the information system workflow will be as follows:

- Off-line tool is installed on laptops.
- User will create new patient and immunization records on the laptop
- At the end of the day, user will upload the file from the laptop to the KDHE server using PHIX.
- On the KDHE server, the file will be received and the necessary information will be transferred to the HAWK smallpox vaccination database (using a text export file). At this point, vaccination records will be available for queries, reports, and updates.
- Updates of existing records, or creation of new records for repeated vaccination events for existing individuals, will be performed using the online access.
- Every night, an XML file will transfer the information from the KDHE server to the CDC, using the CDC Secure Data Network (SDN).

Section 11 - Communications

Communications Goals and Objectives

Goal: The goal of this Kansas NSVP Stage 1 Communications Plan is to enhance awareness and understanding of smallpox vaccine recommendations for selected emergency and medical personnel, in order to help facilitate distribution of vaccine to appropriate persons and to assure public confidence in the public health system.

Objective 1: Incorporate existing CDC pre-event information resources and guidance, to assure consistency with the National Smallpox Vaccination Plan.

Objective 2: Allow for seamless integration of this plan with the state Smallpox Response Plan and the CDC Smallpox Response Plan and Guidelines.

Objective 3: Allow for active participation with local, state and federal partner agencies and organizations throughout any and all aspects of this plan.

Objective 4: Follow established principles of risk and crisis communications, with the intent to build public confidence and trust in the public health process.

Key Messages

Main Message: This is the first phase of our preparation for a smallpox vaccination program. We will continue to work on the details of our plan; in the meantime, as with any emergency, we are prepared to respond today.

Supporting Message: The probability of an intentional release of the smallpox virus is low, but since the consequences of an outbreak would be great, we must be prepared.

This effort strengthens national and state preparedness by making licensed vaccine available to those people who would be called upon to respond to a smallpox release or outbreak.

Smallpox vaccination before a confirmed smallpox case or outbreak provides response teams and other first responders personal protection from smallpox disease. It thus protects these critical health service providers and enables them to take actions necessary to protect the public, which includes identifying people who need to be vaccinated to control the outbreak as well as establishing public vaccination clinics.

By protecting those people who would be initially called upon to respond:

- We further strengthen our ability to protect the public.
- We increase the capacity and capabilities of the public health system and the nation's hospitals to respond to, and control, a smallpox outbreak.

o Messages for people for whom smallpox vaccine is recommended

Healthcare and emergency personnel for whom the vaccine is recommended are encouraged to be vaccinated. These persons should receive the vaccine in order to bolster our society's defenses against a potential terrorist attack.

The decision to be vaccinated can only be made by individuals in consultation with their physicians.

People for whom smallpox vaccine is contraindicated

Due to their pronounced risk of side effects from the vaccine, persons with contraindications should only be vaccinated if they are found to have been exposed to a confirmed case of smallpox.

Healthcare and emergency responders not eligible to receive smallpox vaccine

Because there are side effects to the vaccine, and no evidence that smallpox has been re-introduced into the population, it is appropriate that only those healthcare and emergency personnel who are most likely to respond to a potential case of smallpox be vaccinated in this initial stage.

o The general public

An intentional release of smallpox virus is very unlikely, but because the potential consequences of such a release are so great, the public health system must be prepared.

By protecting those persons who would first respond to a suspected case of smallpox, the ability to protect the public is strengthened.

(Notification and explanation of vaccination clinic operation to media in affected areas.)

Protocols for meeting routine, possible daily, information demands from media (e.g. # of vaccines administered, adverse events, etc.).

In addition to specific measures outlined elsewhere in this plan, KDHE has preexisting policies and procedures applicable for responding to media inquiries of any type. Incoming media calls are transferred to the KDHE Director of Public Information, who coordinates the release of pre-approved information to reporters. In instances where the Director lacks the information necessary to respond to a question, he or she refers the question to the appropriate program expert. The program person may then relay the information to the reporter, either directly or through the Director of Public Information. Program staff then furnishes a subsequent media contact report to the Director as part of standard procedure.

If the Director of Public Information is not available to respond to media calls, program staff has discretion to respond and then furnish a media contact report at a later time. The Director is responsible for notifying Bioterrorism Program staff of when unavailable for extended periods.

The Director of Public Information routinely coordinates all aspects of approval and distribution of news releases and media advisories with program staff. The

Director's job description provides that news releases and responses to media inquiries are to be coordinated with program staff.

Identification of spokespersons for media and select audience communications

The Communication/Public Information contacts will be the KDHE Public Information Officer, Sharon Watson, 785-296-5795, swatson@kdhe.state.ks.us and the bioterrorism Risk Communications Specialist, Don Brown, 785-368-8053, dbrown@kdhe.state.ks.us

Professional and subject matter spokespersons for Kansas will include Dr. Michael Moser, Director of Health; Dr. Gianfranco Pezzino, State Epidemiologist, and Dr. Gail Hansen, Deputy State Epidemiologist. Contact can be made with these individuals through the earlier mentioned communications contacts.

Detailed information on communication materials dissemination

Those receiving the vaccine will receive detailed information through the screening and education procedures described earlier in this plan.

The KDHE Public Information Office maintains an updated media contact list for all news outlets in the state of Kansas. Contact options include mail, telephone, fax, and e-mail.

The KDHE agency and Bioterrorism Websites will be available for posting and distribution of information as needed. The KDHE bioterrorism Writer/Editor is responsible for ensuring prompt posting by the KDHE Webmaster.

The KDHE Risk Communication Specialist has also established a working relationship with the Public Relations Director of the Kansas Hospital Association and will provide relevant communications materials to that individual for distribution to targeted employees and partners of Kansas hospitals.

KDHE can communicate with targeted public health and hospital leaders through the 24-hour Kansas Public Health Information Exchange (PHIX). The secure Webbased communications tool allows KDHE to alert targeted participants through pager messages, asking them to log onto the secure website to view important materials. This system would be a primary means of coordinating communications with the above types of organizations.

Strategies for responding to communication crises

This process is initially met by the protocols listed above related to the daily demands of media relations. The KDHE Public Information Officer will confirm and gain approval from the State Epidemiologist or the Director of Health prior to initial release of any crisis communication materials. The Risk Communications Specialist, housed in the Bioterrorism Program, will act as a liaison between technical staff and the public information office. Effective crisis communication relies on good reliable information from the source. The KDHE Public Information Officer will work within the agency Crisis/Emergency Risk Communication Plan to deliver appropriate and timely communication messages.

Establishment of general NSVP information hot line(s)

The KDHE Public Information Officer and Risk Communications Specialist will utilize the CDC Emergency Hotline and, if necessary, customize the hotline information for Kansas-specific information. This will ensure consistent messages on general phone inquiries. The contact for Kansas use of this CDC resource is Judy Gantt, 404-639-0831. The hotline will provide information to callers in English (888-246-2675), Spanish (888-246-2857) and TTY (866-874-2646).

Healthcare professionals will have access to the KDHE Epi-Hotline by calling 1-877-427-7317.

Coordination of communications

The Kansas Public Health Information Exchange (PHIX) is a secure, Web-based communication system designed to facilitate the rapid exchange of information between KDHE and public health and safety officials throughout the state. The PHIX system allows users to send, receive and discuss information of public health importance in a secure, confidential environment. It also allows for the rapid notification of any and all users in the event of a public health emergency, when the timely distributing of recommendations on investigation, prevention and treatment is critical. This system would be a primary means of coordinating communications with the above types of organizations.

KDHE would also utilize our existing partnership with the Kansas Hospital Association to ensure that information is disseminated through established peer-professional channels to reach health care professionals.

Tailoring messages and materials

Issues related to non-English and low-literacy messages are being initially addressed by CDC Communications staff. If, after reviewing materials developed and offered by CDC, KDHE finds it necessary to customize or expand, the Risk Communications Specialist will undertake that activity.

Emerging communication issues

KDHE's Public Information Officer and the bioterrorism Program's Writer/Editor will monitor, review, and advise others within the agency as appropriate.

Protocol(s) to issue communications with the media.

In events that appear geographically localized, local health departments and hospitals would serve as the "front line" for working with the media on the scene. Our smallpox communications plan calls for rapid and continual contact between the local response entities and the KDHE Public Information Officer, with KDHE providing direction on communication policy. The pre-scripted communications materials created at the state and federal level will be shared with, and distributed through the local responding partners. Materials can be sent electronically through the PHIX system, or downloaded from the KDHE website.

List of educational materials

KDHE will rely heavily upon the materials provided by CDC communications experts, including the growing list of resources at:

http://www.bt.cdc.gov/smallpox

KDHE is developing a Question and Answer document to bring clarity to many of the issues surrounding Stage 1 implementation. A state produced smallpox fact sheet is available, as are a growing number of news release templates.

KDHE Smallpox Phase 1 Q&A (Appendix 6)

KDHE Smallpox fact sheet

KDHE NVSP Stage 1 news release templates (Appendix 7)